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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639

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EXAMINER

WINKLER, ULRIKE

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/889,645

Applicant(s)

WELCH ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 and 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 1 and 5, are attached to the instant Office Action.

Claim Objections

Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 14 not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nebe (WO 96/05846, IDS Paper No. 1), Omar et al. (U.S. Pat. No. 5,696,236, IDS Paper No. 1) and Savage et al. (EP 0 798 003 A2, IDS Paper No. 1)

The instant invention is drawn to a method of removal of infective prion protein from a solution. The method requires the use of a "depth filter" the art recognizes this term as a prefilter that would prolong the useful life of a typical surface/membrane filter. In this instance the filter comprises a porous material having the pore size of less than 6 microns. The filter binding agents are selected from kieselguhr, perlite particles or diatomaceous earth. The liquid comprises a blood plasma product.

Nebe (WO 96/05846, IDS Paper No. 1) teaches the removal of prion from solution utilizing a series of membrane or ultramembrane filters. The method teaches using a prefilter of nylon gauze and nylon membrane filters ranging in size from 2 microns to 0.2 microns (see page 10). The filters can be arranged in a series. The reference indicated that prion particles can be removed from the liquid and as an additional benefit at the same time other infectious material can be removed such as bacteria, viruses and endotoxins (page 6). The reference also teaches that the prefilter alone removed half of the infectious agent (see page 13), indicating that the prion agent has a high binding affinity for the prefilter material. The reference does not disclose the pore size of the nylon premembrane filter. The reference does not teach using kieselguhr, perlite particles or diatomaceous earth in the prefiltration step.

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Omar et al. teaches separating virus from protein solution using an absorbent (binder) that is either diatomaceous earth, perlite or kieselguhr (see claims). The method purifies a human blood plasma solution for the purpose of producing safe blood products (column 1, lines 10-30).

Savage et al. teach a method of removal of viruses from an aqueous liquid containing proteins, the method comprises the steps of passing the liquid through a depth filter formed of matrix comprising porous elements having a size 0.25 –2 microns.

It would have been obvious to one of ordinary skill in the art to utilize a depth filter, which is ordinarily used in the art as a prefilter for ultramembrane filtration (Savage et al. page 2, lines 47-48), for the removal of prion particles from a liquid based on the observation of Nebe which indicated that half of the infectious prion was removed using the nylon premembrane filter (depth filter) indicating that the prion has a high nonspecific affinity for the prefiltration media. One having ordinary skill in the art would have a high expectation of success utilizing the matrices of Omar et al. for the removal of infectious agent from blood plasma products. Therefore, the instant invention is rejected over Nebe, Omar et al. and Savage et al.

Conclusion

Claims 1-13 are rejected.

Claim 14 is objected to and withdrawn from consideration on the merits due to the improper multiple claim dependency (see claim 14 and claim 6).

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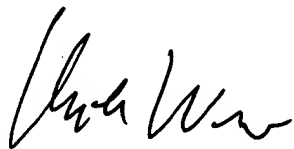
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER 7/19/03